

is respectfully requested in view of the above amendments and following remarks. Claims 18-35 are pending in the application with claims 27-35 currently under examination. By the above amendment, claims 18-26 and 30-34 have been cancelled and claims 28, 29 and 35 have been amended. The above amendments are not to be construed as acquiescence with regard to the Examiner's rejections, and are made without prejudice to prosecution of any subject matter modified and/or removed by this amendment in a related divisional, continuation and/or continuation-in-part application.

Objection to the Drawings

The Action objects to the corrected drawings for allegedly containing amino acid sequences that are not designated by SEQ ID NOs. By the above amendment, the BRIEF DESCRIPTION OF THE DRAWINGS section of the specification has been amended, as requested by the Examiner, to identify the SEQ ID NOs: for sequences depicted in Figures 8, 9 and 11, said SEQ ID NOs: finding support in the specification as originally filed. Applicants respectfully submit that the above-identified application is in compliance with the sequence disclosure requirements of 37 C.F.R. §§ 1.821-1.825 and request reconsideration of this objection.

Rejection Under 35 U.S.C. § 112, First Paragraph, Enablement

Claims 28-35 stand rejected under 35 U.S.C. § 112, first paragraph, for allegedly not being enabled by the instant specification. More specifically, the Action alleges that the specification does not provide sufficient enablement for fragments and variants of the polypeptide set forth in SEQ ID NO: 108 or fusion proteins comprising said fragments and variants.

Applicants respectfully traverse this rejection. As discussed with Examiner Souaya during the telephonic interview conducted February 25, 2003, the skilled artisan in view of the instant specification, would indeed understand how to make and use isolated polypeptides commensurate with the scope of the invention claimed. More particularly, upon accepting that SEQ ID NO: 108 represents an isolated polypeptide having a prostate cancer-associated expression pattern sufficient for use as a diagnostic marker, the skilled artisan would understand that fragments of SEQ ID NO: 108, as well as polypeptides sharing structural identity with SEQ ID NO: 108, as set forth in claims 30-34, can be used, for example, in generating antibodies

having specificity for an amino acid sequence of SEQ ID NO: 108, and thus in the detection of prostate cancer according to Applicants' disclosure. However, as set forth above, and without prejudice to prosecution of this subject matter in a related application, Applicants have cancelled claims 30-34 at this time in order to advance prosecution of the subject application.

Reconsideration and withdrawal of this rejection under 35 U.S.C. § 112, first paragraph, is thus respectfully requested.

Rejection Under 35 U.S.C. § 112, First Paragraph, Written Description

Claims 28-35 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter which is not described in the specification in such a way as to reasonably convey to the skilled artisan that Applicants were in possession of the claimed invention at the time of filing the instant application. More specifically, the Action alleges that the specification does not adequately describe fragments and variants of the polypeptide set forth in SEQ ID NO: 108 or fusion proteins comprising said fragments and variants.

Applicants respectfully traverse this rejection. As discussed with Examiner Souaya during the telephonic interview conducted February 25, 2003, the skilled artisan, in view of the instant specification, would understand that Applicants were in possession of the claimed fragments of SEQ ID NO: 108, as well as polypeptides sharing structural identity with SEQ ID NO: 108, as set forth in claims 30-34, for example on the basis that such polypeptides can be used to generate antibodies having specificity for SEQ ID NO: 108, and thus be capable of detecting the presence of prostate cancer according to Applicants' disclosure. However, as set forth above, and without prejudice to prosecution of this subject matter in a related application, Applicants have cancelled claims 30-34 at this time in order to advance prosecution of the subject application. Reconsideration and withdrawal of this rejection under 35 U.S.C. § 112, first paragraph, is thus respectfully requested.

Provisional Obviousness-Type Double Patenting Rejection

Claims 17-34 stand provisionally rejected under the judicially created doctrine of obviousness-type double-patenting as being unpatentable over claim 2 of copending Application Nos. 09/568,100, 09/636,215, 09/593,793, and 09/605,783.

Applicants respectfully traverse this rejection on the basis that the subject matter elected and under examination in Application Nos. 09/568,100, 09/636,215, 09/593,793, and 09/605,783 is unrelated to the subject matter of the instant claims.

With regard to Application No. 09/568,100 (Applicant Ref. 427C13), Applicants elected Group I, claims 1-3, 14-17, 64 and 65, and SEQ ID NO:113, which sequence is unrelated to the prostate cancer sequence of SEQ ID NO: 108 that is currently under examination in the instant application. Applicants amendment effecting removal of reference to SEQ ID NO: 108 and cancellation of non-elected claims of Application 09/568,100 will be filed in due course, a copy of which will be provided at the time allowable subject matter is identified in the instant application.

With regard to Application No. 09/636,215 (Applicant Ref. 427C17), Applicants elected Group I, claims 4-8, 16 and 58-60, and SEQ ID NO:110 for examination, which sequence is unrelated to the prostate cancer sequence of SEQ ID NO: 108 that is currently under examination in the instant application. Claim 2 is no longer pending in Application No. 09/636,215. Applicants' amendment effecting cancellation of claim 2 of Application No. 09/636,215 was filed December 2, 2002, a copy of which will be provided at the Examiner's request.

With regard to Application No. 09/593,793 (Applicant Ref. 427C15), Applicants elected Group VI (claims 18-20, 22, 25-31), and the species of SEQ ID NO: 113 for examination, which sequence is unrelated to the prostate cancer sequence of SEQ ID NO: 108 that is currently under examination in the instant application. Claim 2 is no longer pending in Application No. 09/593,793. The Examiner's Amendment effecting cancellation of claim 2 of Application No. 09/593,793 was filed July 18, 2002 in the Notice of Allowance, a copy of which will be provided at the Examiner's request.

With regard to Application No. 09/605,783 (Applicant Ref. 427C16), Applicants elected Group VII, claims 35-37, and SEQ ID NO:113 for examination, which sequence is unrelated to the prostate cancer sequence of SEQ ID NO: 108 that is currently under examination in the instant application. An amendment effecting cancellation of claim 2 of Application No. 09/605,783 will be filed in due course, a copy of which will be provided at the time allowable subject matter is identified in the instant application.

Accordingly, Applicants respectfully submit that the subject matter of the claims under examination in the instant application is clearly distinct from the subject matter under examination in Application Nos. 09/568,100, 09/636,215, 09/593,793, and 09/605,783. Reconsideration of this rejection is thus respectfully requested.

Rejection Under 35 U.S.C. § 102(a)

Claims 28, 29, 33, and 34 stand rejected under 35 U.S.C. § 102(a) as allegedly being anticipated by Accession number CAA69358 (September 15, 1997). More specifically, the Action alleged that Accession number CAA69358 discloses an amino acid sequence sharing 22 consecutive residues in common with SEQ ID NO: 108.

Applicants respectfully traverse this rejection. Claims 33 and 34 have been cancelled, without prejudice or acquiescence. Moreover, as set forth above, claims 28 and 29 have been amended, for purposes of clarity, to specify that the claimed fragments of SEQ ID NO: 108 comprise at least 25 (claim 28) or 50 (claim 29) consecutive residues of SEQ ID NO: 108. As the cited reference fails to teach or suggest an isolated polypeptide comprising at least 25 or 50 consecutive residues of SEQ ID NO: 108, the cited reference fails to anticipate the currently claimed invention. Reconsideration and withdrawal of this rejection is respectfully requested.

Rejection Under 35 U.S.C. § 103(a)

Claim 35 stand rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Accession number CAA69358 in view of Haldenwang (WO 93/03156). More specifically, the Action alleges that it would have been obvious to the skilled artisan to construct a fusion protein comprising the protein taught by Accession number CAA69358 with a protein stabilization sequence, as described in Haldenwang.

Applicants respectfully traverse this rejection. Claim 35 has been amended, as set forth above, to depend from claims 28 and 29, which are drawn to isolated polypeptides comprising at least 25 or 50 consecutive amino acids, respectively, of SEQ ID NO: 108. As discussed above, CAA69358 fails to either teach or suggest any isolated polypeptide comprising at least 25 or 50 consecutive amino acid residues of SEQ ID NO: 108, and these deficiencies of CAA69358 are in no way remedied by the disclosure of Haldewang. Accordingly, as neither CAA69358 nor Haldewang provide disclosure that would lead the skilled artisan to any isolated

polypeptide comprising at least 25 or 50 consecutive amino acid residues of SEQ ID NO: 108, this combination of reference fail to render obvious a fusion protein comprising at least 25 or 50 consecutive amino acid residues of SEQ ID NO: 108, which is the subject matter of currently pending claim 35. Reconsideration and withdrawal of this rejection is thus respectfully requested.

The Commissioner is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "**Version With Markings to Show Changes Made.**"

All of the claims remaining in the application are now believed to be in condition for allowance. Favorable consideration and a Notice of Allowance are earnestly solicited.

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Specification:

Paragraph beginning at page 10, line 1, has been amended as follows:

Figure 8 illustrates the results of epitope mapping studies on P501S. The peptides used in the study are shown from left to right at the bottom of the figure, as follows: MDRLVQRPGTRAVYLASVA (SEQ ID NO: 489), YLASVAAFPVAAGATCLSHS (SEQ ID NO: 490), TCLSHSVAVVTASAALTGFT (SEQ ID NO: 491), ALTGFTFSALQILPYTLASL (SEQ ID NO: 492), YTLASLYHREKQVFLPKYRG (SEQ ID NO: 493), LPKYRGDTGGASSEDLSMIS (SEQ ID NO: 494), DSLMTSFLPGPKPGAPPNG (SEQ ID NO: 495), APFPNGHVGAGGSGLLPPPA (SEQ ID NO: 496), LLPPPAPALCGASACDVSVRV (SEQ ID NO: 497), DVSVRVVVGEPTEARVVPGR (SEQ ID NO: 498), RVVPGRGICLDLAILDSAFL (SEQ ID NO: 499), LDSAFLLSQVAPSLFMGSIV (SEQ ID NO: 500), FMGSIVQLSQSVTAYMVSAA (SEQ ID NO: 501).

Paragraph beginning at page 10, line 2, has been amended as follows:

Figure 9 is a schematic representation of the P501S protein (SEQ ID NO: 113) showing the location of transmembrane domains and predicted intracellular and extracellular domains.

Paragraph beginning at page 10, line 7, has been amended as follows:

Figure 11 shows the results of an ELISA assay to determine the specificity of rabbit polyclonal antisera raised against P501S. The depicted sequence corresponding to peptide P501S 306-320 is set forth in SEQ ID NO: 519 and the sequence corresponding to P501S 296-320 is set forth in SEQ ID NO: 520.

In the Claims:

Claims 18-26 and 30-34 have been canceled.

Claims 28, 29 and 35 have been amended as follows:

28. (Amended) An isolated polypeptide comprising the amino acid sequence of SEQ ID NO:108, or a fragment thereof comprising at least 10-25 consecutive amino acid residues of SEQ ID NO:108.

29. (Amended) An isolated polypeptide comprising the amino acid sequence of SEQ ID NO:108, or a fragment thereof comprising at least 20-50 consecutive amino acid residues of SEQ ID NO:108.

35. (Amended) A fusion protein comprising a polypeptide according to any one of claims 18-25²⁷⁻²⁹.